

SUMMARY OF TELEPHONIC INTERVIEW

Attendees, Date and Type of Interview

The telephonic interview was conducted on June 9, 2010 and attended by Applicant's representatives Mark R. Benedict and Raymond D. Smith, and Examiner Laura J. Schuberg.

Exhibits and/or Demonstrations

None

Identification of Claims Discussed

None

Identification of Prior Art Discussed

Kraus et al. (U.S. Patent No. 5,143,838);
Piet et al. (1990 *Transfusion* **30**:591-598); and
Anderle et al. (U.S. Patent Application publication No. 2003/0133829)

Proposed Amendments

None

Principal Arguments and Other Matters

The following arguments were made in connection with the obviousness rejections.

Applicant's representatives argued that Piet et al. teaches methods that are not suitable for the fractionation of prothrombin complex coagulation factors and would not be an obvious choice for a skilled artisan with regard to generation of thrombin. In particular, based on the data presented by Piet et al. (Figure 3, in particular) and the teachings of Piet et al. at page 596, the skilled artisan would not combine the teachings of Piet et al. with Kraus because the solvent/detergent (S/D) treatments presented by Piet et al. resulted in a reduced recovery of Prothrombin complex concentrate.

Applicant's representatives pointed out that Anderle et al. teaches away from a S/D inactivation step that does not include the specific combination of a carboxylic acid ester and detergent. The Examiner was receptive to this argument and even pointed out that Anderle et al.

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specifically concluded at paragraph [0086] that “A composition comprising a carboxylic acid ester, in particular acetyl triethyl citrate and tributyl or triethyl citrate has a strong inactivating effect on pathogens and is however sufficiently gentle and safe in order to preserve a high level of protein function and activity to the contrary of the known combinations as for example Tween 80 with TNBP which reduces the activity of the protein.” Thus, one of ordinary skill in the art would be discouraged from using the presently claimed S/D treatment that specifically uses TNBP as solvent.

Results of Interview

Applicant’s representatives proposed to submit a response to the Office Action and an Affidavit to address the issues raised by the obviousness rejections.